

Remarks

Disposition of the Claims

Upon entry of the current amendment, Claims 1 through 8, 11, and 13 are pending. Claims 1 through 8 and 11 have been amended. Claims 9, 10 and 12 have been cancelled. Claim 13 is new.

Claims 1 through 8 and 11 have been amended to include pharmaceutically acceptable salts. Support for this can be found on page 12, paragraphs 4 through 6.

Claim 1 has been amended to replace R_1 with R_1 , R_2 with R_2 , R_3 with R_3 , and R_4 with R_4 . Claims 2, 6, 7, and 8 have been amended to be consistent with Claim 1. Support for these amendments can be found in formula (I) which shows these variables without subscripts.

Claim 1 has been amended to replace the group "-ON" in the definition of R_3 with a cyano group. Support for this amendment can be found page 2, lines 11-12 and in Examples 11-16 of the specification.

Claims 2 and 4 have been amended to correct a typographical error and remove the period in the line before the structure.

Claim 8 has been amended to remove from the definition of R_4 the phrase "and preferably methyl or ethyl."

New Claim 13 limits R_4 to methyl or ethyl. Original Claim 8 supports new Claim 13.

No new matter has been added.

Rejection of Claims 10-12 Under 35 U.S.C. § 112, First Paragraph

The Examiner has stated that Claims 10-12 fail to comply with the enablement requirement.

Applicants have cancelled Claim 10, and although Applicants disagree with the Examiner's assessment that Claim 12 is not enabled, Applicants have cancelled Claim 12 in order to expedite prosecution. The cancellation of Claims 10 and 12 renders the rejection of these claims moot.

In regard to Claim 11, the Examiner has stated that the specification does not enable a person of skill in the art to use the invention commensurate in scope with the claim. In addition the Examiner states that there is no screening assay.

Applicants disagree with the Examiner's opinion that Claim 11 is not enabled. Claim 11 claims a pharmaceutical composition comprising a compound of the invention and a

pharmacologically and pharmaceutically acceptable additive. In the section of the specification labeled "Experimental Part-Pharmacological" on page 19, line 11 to page 23, line 3, Applicants list pharmacologically and pharmaceutically acceptable additives that may be used in the claimed pharmaceutical compositions and give examples of particular compositions. In addition, on page 20, line 19 to page 21, line 2 of the specification, Applicants disclose appropriate doses and dosing schedules for the compounds of the invention.

Moreover, in the section of the application labeled "Experimental Part-Biological" on page 17, last line to page 19, line 10 of the specification, Applicants have provided two *in vitro* assays and one *in vivo* model for testing whether a compound is a RXR antagonist. The *in vivo* model measures the activity of RXR antagonists of the invention in lower plasma parameters such as triglycerides and blood sugar. Applicants have indicated which compounds of the invention performed best in this *in vivo* model, thereby providing guidance to one skilled in the art as to which structural feature in the compounds of the invention render the desirable biological activity.

Given the list of acceptable additives and the guidance regarding the most preferred compounds of the invention in the specification, a person of skill in the art would be able to prepare and use pharmaceutical compositions of the invention without undue experimentation, and Applicants' Claim 11 is enabled. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Rejection of Claims 1-12 Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected Claims 1-4 and 6-8 because the structures in the claims have the variables R₁, R₂, R₃, and R₄, whereas the definition of the variables are for R₁, R₂, R₃, and R₄. Applicants have amended the variables to correspond with the structures.

The Examiner has rejected Claim 1 because the definition of R₃ includes the term "-ON" which is unclear. The term "-ON" is a typographical error. Applicants have replaced the term with -CN. Support for this amendment can be found on page 2, lines 11-12 and in Examples 11-16 of the specification.

The Examiner rejected Claim 6 because the definition of R₃ included a cyano group for which there was insufficient antecedent basis in Claim 1. Applicants amendment to the definition of R₃ in Claim 1 provides sufficient antecedent basis for the cyano group in Claim 6.

The Examiner has stated that Claims 2 and 4 are indefinite because they contain a period in the middle of the claim before the structure. Applicants have amended the claims to remove the period in the middle of the claim.

The Examiner has rejected Claim 8 because the claim recites a broad limitation "C1-C7-alkyl" and a narrower limitation that falls within the range of the broader limitation. Applicants have amended Claim 8 to delete the narrower limitation and have claimed the narrower limitation in new Claim 13.

Claims 9, 10 and 12 have been cancelled rendering the rejections of these claims moot.

Rejection of Claims 10 Under 35 U.S.C. § 101

The Examiner has rejected Claim 10 because it recites a use without setting forth any steps involved in the process. Applicants have cancelled Claim 10 rendering the rejection moot.

Conclusion

It is respectfully submitted that this application is in condition for allowance.


If there are any remaining issues or the Examiner believes that a telephone conference with the Applicants' Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617)-871-7802.

Applicants have requested a 2 month extension of time to respond to the Office Action and have included the petition fee. Applicant believes that no additional fees are due with this filing. However, if any fees are required, the Commissioner is authorized to charge Deposit Account No. 50-4409 in the name of Novartis for any fees due.

Respectfully submitted,

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